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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 25647-410611

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on June 21, 2007

Signature

Typed or printed name: George H. Gerstman

Application Number	Filed
10/691,823	10/23/2003

First Named Inventor: Grewe et al.

Art Unit	Examiner
3736	J. Hoekstra

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☒ attorney or agent of record. Registration number 22,419
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

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312-460-5567
Telephone number

June 21, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

The current claims are as listed in the Amendment dated December 29, 2006.

The examiner has rejected claims 1-39 as unpatentable over Hayzelden et al. (US 2002/0165534 A1) in view of Klima et al. (US 6,273,876 B1).

The present invention concerns a novel, steerable guidewire 12 having a deflectable tip. The guidewire of claim 1, for example, comprises an elongated, flexible tubing 16 having proximal and distal portions, with a flexible, helical coil 18 provided, having multiple turns and proximal and distal ends. By this invention, as defined in claim 1, the helical coil has a rectangular, cross sectional configuration and has continuous undulations. The undulations of adjacent coil turns interlock with each other, as shown for example below in Fig. 2a as helical coil 18.

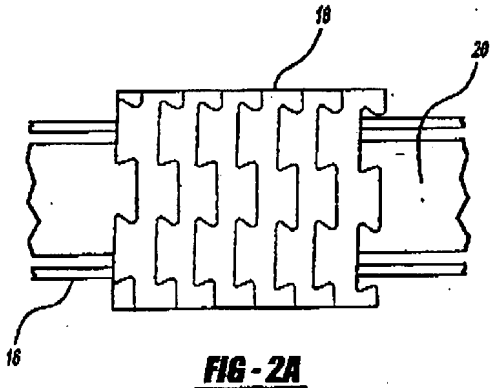


FIG - 2A

Lateral bending of the catheter tip is done with ease, because helical coil 18 is of a helical nature, and the respective helical coils can separate from each other on one side of the catheter when the catheter tip is bent in the opposite direction. However, the torque or rotational resistance of the guidewire system of claim 1 is greatly increased over a normal guidewire member having a flexible, helical coil because of the interlocking action provided by the sinusoidal positive and negative peaks in which (per claim 1) ". . . the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns."

Thus, claim 1 and its dependent claims define a guidewire which retains good lateral flexibility at the area of its helical coil, but, which exhibits increased torque/rotation resistance, which is a highly desirable combination of features.

The Examiner has very clearly misinterpreted the primary reference to Hayzelden et al. resulting in a clear factual deficiency in the Examiner's rejection. For example:

1. All of Applicant's claims concern a "steerable guidewire." In his rejection, the Examiner states that Hayzelden et al. teaches a "steerable guidewire." This is factually incorrect. The Hayzelden et al. reference concerns an ablation catheter having electrodes and lacking many of the claimed attributes of Applicant's steerable guidewire.

2. All of Applicant's claims make it clear that Applicant's invention is a steerable guidewire, not an ablation catheter which serves an entirely different purpose and is structurally significantly different.

3. All of Applicant's claims call for "a flexible helical coil." In paragraph 4 of the Office Action, the Examiner states that Hayzelden et al. has "a flexible helical coil (82) having multiple turns and having proximal and distal ends (as best seen in Figs. 2 and 3)." This is incorrect. Element 82 of Hayzelden et al. is not "a flexible helical coil" as contended by the Examiner but is instead a wire braid which is structurally and functionally significantly different from a helical coil.

4. Applicant's claims 1 to 18, 23 and 25-39 call for a retaining ribbon for the steerable guidewire. In paragraph 4 of the Office Action, the Examiner states that Hayzelden et al. has "a retaining ribbon (54)." This is factually incorrect. Element 54 of

Hayzelden et al. is not "a retaining ribbon" as contended by the Examiner but is instead a steering tendon.

5. Even the Examiner's use of the Klima et al. reference as a secondary reference does not support the Examiner's rejection. In addition to Hayzelden et al. not disclosing a steerable guidewire (but instead disclosing an ablation catheter), Klima et al. is also not a steerable guidewire, but is instead a catheter having an open proximal end and an open distal end.

6. The Examiner points to Figs. 11-13 and 15 of Klima et al. and contends these figures show continuous undulations taking the form of a sinusoidal wave as claimed by Applicant and states that "the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns." The Examiner is factually incorrect. Contrary to the Examiner's statement, the positive peaks of adjacent turns of the coils of Klima et al. do not engage the negative peaks of adjacent turns as required by the claims. In actuality, the adjacent turns of Klima et al. are expressly separated by a slot 1084 (Figs. 14A to 14B) which is filled with a material that forms the outer jacket. Serpentine slot 1084, which expressly separates the positive peaks of adjacent turns from the negative peaks of adjacent turns is a significant aspect of Klima et al.'s disclosure and is discussed in most detail in column 10, line 64 to column 11, line 21 of Klima et al. It is clear that Klima et al. actually teaches away from having the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns.

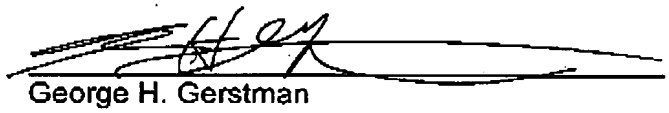
7. It is seen that there are clear factual errors in the Examiner's interpretation of the references. The references themselves do not disclose what the Examiner states the references disclose, but instead disclose structure that is significantly different from

the structure set forth in Applicant's claims. Thus even if the combination of references were proper (although it is not), the combination would not come close to teaching the subject matter of the claims.

In view of the above, reversal of the Examiner's rejection is respectfully requested.

Respectfully submitted,

SEYFARTH SHAW LLP



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